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Digital radiographic preoperative planning and postoperative monitoring of total hip replacements

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Digital versus analogue preoperative planning of total hip arthroplasties

A randomized clinical trial of 210 total hip arthroplasties

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Abstract

Introduction

The objective of this randomized clinical trial was to compare clinical and technical results of digital preoperative plans for primary total hip arthroplasties with analogue planning.

Methods

Two hundred and ten total hip arthroplasties were randomized. All plans were constructed on standardized radiographs by the surgeon who performed the arthroplasty the next day. The main outcome was accuracy of the preoperative plan. Secondary outcomes were operation time and a radiographic assessment of the arthroplasty.

Results

Digital preoperative plans were more accurate in planning the cup ($p < 0.05$), and scored higher on the postoperative radiological assessment of cemented cup ($p = 0.03$) and stem ($p < 0.01$) components. None of the other comparisons reached statistical significance.

Conclusion

We conclude that digital plans slightly outperform analogue plans.



Introduction

Preoperative planning of a total hip arthroplasty is an important part of the surgical procedure. During this process, the surgeon searches for optimal fit of the hip implants and for the best technique to reconstruct leg length and the position of the centre of rotation, both of which are dependent on the implant size and positioning. Preoperative planning forces the surgeon to think three-dimensionally and is thought to improve surgical precision, shorten the length of the procedure and reduce the incidence of complications.¹⁻⁶ Preoperative planning also provides the surgeon with a tool to ascertain that the correct prosthetic component sizes are available, and can be of assistance in logistic and stock management or the operation theatres.

The potential difficulty to accurately determine the magnification factor of the radiograph is one of the problems in analogue preoperative planning of total hip arthroplasties. In addition, the use of templates with standard magnifications does not always allow for accurate correction of the magnification factor.⁷⁻⁹ Digital radiographs are replacing conventional radiographs to a growing extent. This allows the orthopaedic surgeon to perform the planning on screen using specialized software. These applications enable the surgeon to correct the magnification factor with more accuracy and reliability. Although this might sound appealing, it is unclear what the actual advantages of digital preplanning are.

The objective of this randomized clinical trial was to compare both clinical and technical results of digital preoperative plans for primary total hip arthroplasties with analogue planning. Our first hypothesis was: Digital preoperative planning is more accurate than analogue preoperative planning in predicting intraoperatively implanted component sizes of the cup and stem in primary total hip arthroplasty (primary outcome). Our second hypothesis was: using digital preoperative planning results in shorter operation times, fewer leg length differences, and higher scores on radiographic evaluation (secondary outcome).

Methods

A sample size calculation was performed. A minimum of 182 patients would be required for 80% power to detect a difference in success rate of 20% in order to predict the correct component size (assuming a success percentage of 60% in the analogue group versus 80% in the digital group).

The day before surgery an independent observer evaluated for inclusion all patients who were admitted for a primary total hip arthroplasty. All primary total hip arthroplasties performed in the period between March 2003 and April 2005 were eligible for inclusion. Exclusion criteria were fractures, a history of previous surgery on the pelvis or proximal femur with disturbance of the bony anatomy of the hip joint (such as pelvic osteotomies, Girdlestone procedures, revision surgery, etc.) and

combined procedures such as removal of formerly implanted fixation material before implanting the prosthesis in the same stage.

All patients gave informed consent and were randomized (flipping a coin) to either analogue or digital planning by an independent observer who was blinded for any information about the patient. The orthopaedic surgeon who would perform the operation was informed of the result of the randomization and constructed an analogue or digital plan accordingly.

All patients had a standardized plain pelvic radiograph (film-focus distance 115 cm) taken at the preoperative screening in supine position with both legs in maximum internal rotation. The calibration object (a 28 mm prosthetic femoral head) was positioned between the legs of the patient at the anteroposterior level of the greater trochanter (**fig. 1**). This bony structure is best palpable when the femoral anteversion is neutralized with the legs in 20° internal rotation.^{6,10} If the patient was unable to do so, the calibration object was placed 1 to 2 cm higher than the greater trochanter.

The patient's age, sex, Body Mass Index (BMI), and the type of prosthesis to be implanted were recorded. On the preoperative radiographs presence of developmental dysplasia of the hip was determined by measuring the Wiberg angle and, if present, avascular necrosis with collapse of the femoral head was scored, since both conditions potentially interfere with both the planning as well as with the surgical procedure. The Harris Hip Score was taken both preoperatively and postoperatively at different intervals. Preoperative and postoperative leg length differences were clinically assessed, and presence or absence of hip joint contractures were determined. The level of experience of the performing surgeon (i.e. resident or consultant) was also

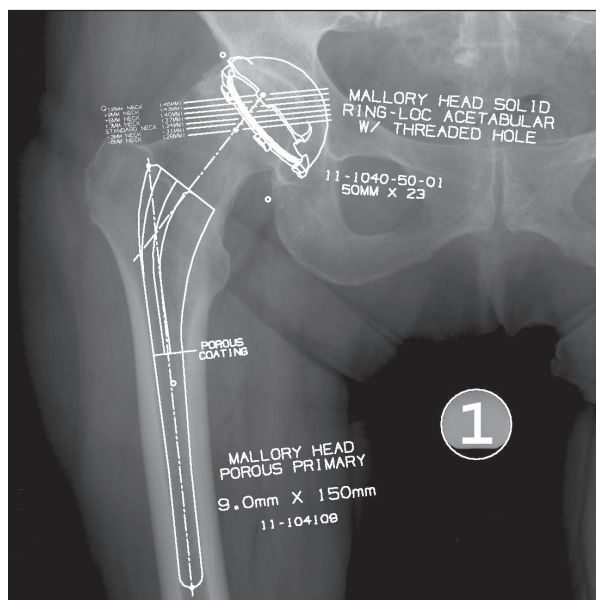


Figure 1. Plain pelvic radiograph with calibration object (1) placed between the patient's legs at the estimated anteroposterior level of the hip joint. The cobalt chromium calibration object has a known diameter of 28 mm and is used to adjust the magnification of the digital templates to the magnification factor of the radiograph.



recorded, as well as the presence of rheumatoid arthritis or a total hip prosthesis on the contralateral side. All above mentioned measurements and observations were performed by an independent observer, who was not aware of the group to which the patient was allocated.

The Mallory Head prosthesis with a metal-backed cup was used for all non-cemented total hip arthroplasties, while the Scientific Hip Prosthesis (SHP) with an all-polyethylene cup was used for all cemented total hip arthroplasties (Biomet NL, Dordrecht, the Netherlands). The Mallory Head cups were available in ten sizes and the stems were available in eight sizes. Both the SHP cups and stems were available in seven sizes.

Analogue or digital plans were constructed by the surgeon who performed the arthroplasty the next day. For analogue planning the projected diameter of the 28 mm calibration object on the pelvic radiograph was measured with a calliper. A standardized table was then used to determine which magnification (110%, 115% or 120%) of templates should be used.

If the arthroplasty was allocated to digital planning, the orthopaedic surgeon used digital calibration of the digital radiograph with the same calibration object. The preoperative plan was constructed using the commercially available software package HyperORTHO™ (Rogan-Delft B.V., Veenendaal, the Netherlands). After completing the analogue or digital preoperative plan, the chosen implant sizes were recorded in the patient's medical record.

The analogue and digital groups were compared on several outcomes. The main outcome was accuracy of the preoperative plan to predict the correct size of the implant. A margin of error of one component size was allowed. A comparison was also performed to see if the choice of planning procedure had any effect on operation times, as recorded by the anaesthesiologist. To conclude, a radiographic assessment of the arthroplasty was performed by the surgeon on the 5-day postoperative standardized plain pelvic x-ray. Scoring was performed on radiographic result of the arthroplasty with respect to cup and stem size (evidently too small or too big), position of the stem (evident varus or valgus) and reconstruction of desired leg length (more than 1 cm difference between desired and resulting leg length).

Additionally, intraobserver reliability of digital preoperative planning was determined. Eight different orthopaedic surgeons performed the planning procedure twice on a series of 34 radiographs (21 cemented and 13 non-cemented arthroplasties). The period between the two consecutive measurements was 4 weeks. To determine interobserver reliability, all 34 radiographs were used again for construction of a preoperative plan by eight different orthopaedic surgeons who did not make the first plan. None of these surgeons were involved in the actual surgery of these patients.

For continuous variables a univariate analysis was performed using the Student t-test for independent samples. The Chi-square and Fisher's exact test were used to analyze categorical variables. The weighted kappa was used to measure chance-corrected interobserver and intraobserver reliability. While no absolute definitions are possible,

we rated the strength of agreement with scores of 0.20 or less as “poor”, 0.21 to 0.40 as “fair”, 0.41 to 0.60 as “moderate”, 0.61 to 0.80 as “good” and 0.81 to 1.00 as “very good” 11. All statistics were performed using SPSS version 12.0 (SPSS Inc, Chicago).

Results

Two hundred and ten primary total hip arthroplasties were included in the study. All interventions were primary arthroplasties for osteoarthritis. The characteristics of the patients in the analogue and digital groups are summarized in **table 1**.

With regard to the primary outcome, digital preoperative plans performed only better on accuracy of planning of the cup ($p = 0.042$) (**table 2a**). The secondary endpoint comparisons of postoperative radiological assessment of the choice of implanted cemented cup ($p = 0.03$) and stem ($p < 0.01$) components were statistically significant and both in favour of digital planning. None of the other variables reached statistical significance, but it was striking that all scored favourably for digital preoperative planning, except for the presence of a postoperative leg length difference (**table 2b**). Three intraoperative complications were recorded in the analogue group: one intraoperative femoral shaft fracture, one procedure where cement entered the cup, and one procedure with more than 2 litres blood loss. The two complications in the digital group were: more than 2 litres blood loss and a lesion of the sciatic nerve with persistent symptoms.



Table 1. Patient Demographics

Variable	Analogue	Digital
Number of patients	106	104
Age (SD)	65 (13.5)	65 (14.9)
Female gender	77/106 (73%)	67/104 (64%)
Planning & operation by resident	53/106 (50%)	63/104 (61%)
Cemented (# of cemented procedures)	79/106 (75%)	73/104 (70%)
Operated side (% left)	50/106 (47%)	44/104 (42%)
BMI (SD)	27.7 (4.5)	27.7 (4.7)
Rheumatoid Arthritis	8/106 (8%)	16/104 (15%)
AFN	31/106 (29%)	37/104 (36%)
Contralateral prosthesis	25/106 (24%)	27/104 (26%)
Wiberg angle (SD)	37 (13.9)	40 (11.5)
Preoperative HHS	51 (22.4)	49 (21.2)
Preoperative LLD	29/106 (27%)	27/104 (31%)
Presence of contracture	23/106 (22%)	17/104 (16%)

SD = standard deviation; BMI = body mass index; AFN = avascular necrosis of the femoral head; HHS = Harris Hip Score; LLD = leg length difference

Table 2a. Primary Outcome

Outcome	Total		Cemented		Non-cemented		P
	analog	digital	p	analog	digital	p	
Correct cup	73 / 106 (69%)	84 / 104 (81%)	0.047	55 / 79 (70%)	58 / 73 (80%)	0.166	0.127
Correct stem	72 / 106 (68%)	79 / 104 (76%)	0.195	57 / 79 (72%)	61 / 73 (84%)	0.092	0.847

Table 2b. Secondary Outcome

Outcome	Total		Cemented		Non-cemented		p
	analog	digital	p	analog	digital	p	
OT (SD)	111 min (31)	106 (24)	0.162	114 (31)	112 (24)	0.581	0.101
EDPS	3 / 106 (3%)	2 / 104 (2%)	1.000*	3 / 79 (4%)	1 / 73 (1%)	0.621*	–
LLD > 1 cm	20 / 106 (19%)	23 / 104 (22%)	0.560	13 / 79 (16%)	17 / 73 (23%)	0.290	0.549
Dev X-cup	6 / 106 (6%)	3 / 104 (3%)	0.498*	6 / 79 (8%)	0%	0.029*	0.240*
Dev X-stem	7 / 106 (7%)	2 / 104 (2%)	0.170*	8 / 79 (10%)	0%	0.007*	1.000*

*OT = operation time; SD = standard deviation; EDPS = evident deviance in position of the stem (either varus or valgus); LLD > 1 cm = postoperative leg length difference of 1 cm or more; Dev X-cup = evident undersizing or oversizing of cup component on postoperative radiograph; Dev X-stem = evident undersizing or oversizing of stem component on postoperative radiograph; * = Fisher's exact test used.*

Table 3. Intra and inter observer reliability of preoperative planning

Prosthesis	Component	Intra	Inter
Non-cemented	Cup	0.71	0.69
	Stem	0.77	0.44
Cemented	Cup	0.42	0.33
	Stem	0.64	0.29

*Intra = intraobserver measurements; Inter = interobserver measurements.
All values are weighted kappas.*

Interobserver and intraobserver reliability measurements for the planning procedure are summarized in **table 3**. The planning of non-cemented prostheses has a higher kappa value on average than the planning of cemented prostheses. Using the ratings given in the Materials section, the non-cemented Mallory Head scores three times “good” and one time “moderate” (interobserver reliability of planning the stem). The cemented SHP scores two times “fair” (interobserver reliability of both cup and stem), one time “moderate” (intraobserver reliability of planning the cup) and one time “good” (intraobserver reliability of planning the stem).

Discussion

A previous study we conducted also compared digital versus analogue preoperative planning.¹² At that time the digital preoperative plans could not be constructed by the orthopaedic surgeon himself because the software package was in an early developmental phase. Considering both the fact that the results of that study were very similar for digital and analogue planning, and the possible source for confounding in favour of analogue plans, we deemed it necessary to conduct a randomized clinical trial.

The protocol we use to correct for the magnification in digital preoperative planning has been validated.¹³ It was proven to be accurate, but a margin of error of -3% to +3% was to be expected (95% range of radiographs). Still, this margin of error is just reflecting clinical practice and is therefore not a source of bias.

A point of discussion in this study is that it does not enable us to draw conclusions on potential long-term beneficiary effects of more accurate planning. We decided that long-term effects would be investigated if large differences were found on the main outcome measures of the current study. Although we found significant differences in favour of digital preplanning, the actual differences were not large, so before clinical benefits at long-term follow-up resulting from digital preoperative planning can be expected, more fundamental research should be done to improve the accuracy first.

Another issue of debate is the choice of our primary endpoint. We considered a preoperative plan successful if it predicted the correct component sizes. From the perspective of improving stock control of hospitals and manufacturers, this is certainly a preferable endpoint. To obtain optimal fit of the prosthetic components it also seems to be a correct choice. Although optimal fit also relates to a biomechanical aspect of successful hip replacement, it could be debated from a broader biomechanical point of view that the endpoint should be based on how favourable the artificial joint is in terms of hip joint contact forces, or similar biomechanical quantities. It would be valuable if future research would address this issue. Although this endpoint is commonly used, it could in theory be biased by the surgeon's confidence in his planning technique. We judged this not to be the case in our hospital, since both techniques had been employed interchangeably prior to this study.



It might be debated whether or not the postoperative radiographic evaluation of the THR should have been standardized. It was considered that some surgeons may maximize the size of the cup to maximize polyethylene thickness while other surgeons may settle for a smaller size cup. This might have led to problems if this was not taken into consideration at the postoperative evaluation. In our opinion, standardization of the evaluation procedure would never sufficiently allow for these differences between surgeons to be taken into account. We have therefore specifically chosen for the operating surgeon to also perform the postoperative evaluation. Although the evaluation was therefore not blinded, the surgeon's evaluation was not accessible to others than the data manager in order to encourage the surgeon to be as objective as possible in his evaluation.

The kappa values of the interobserver and intraobserver reliability measurements of the preoperative plans were never "very good" (0.81 to 1.00). The inter observer reliability of cemented components scored worst and was graded only to be "fair". In an attempt to explain the figures, it is very probable that differences between surgeons will become more pronounced since the cement mantle provides an extra variable to consider, leading to a decrease in inter observer reliability. Preplanning of non-cemented components had overall higher kappa values than preplanning of cemented components. Planning of non-cemented components is dependent on the use of clear bony landmarks, which adds to both the interobserver and intraobserver reliability. The fact that the intraobserver reliability is always better than the interobserver reliability has at least one clear implication: preoperative planning should always be done by the operating surgeon himself.

The accuracy of preoperative templating has been the subject of other studies.^{5,9,14} As far as the authors are aware of, this study is the first randomized clinical study to investigate the difference between digital and analogue preoperative planning. Possible confounders which were known, such as experience of the surgeon, were measured to enable us to detect failure of randomisation and to keep the possibility of adjustment for confounding in the analysis if necessary (which turned out not to be necessary). The type of prosthesis (cemented or non-cemented) was considered to be a plausible effect modifier and was treated as such in the analysis. The most relevant effect modification was induced by the type of stem (cemented or non-cemented) as previously described.⁹

We conclude that digital preoperative plans tend to outperform analogue plans. Statistical significant differences were found for accuracy of planning of the cup, and the radiological assessment on the postoperative radiograph concerning the implanted cemented cup and stem components. Future research should address the value of digital preoperative planning from a more biomechanical perspective

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